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NOTICE OF ALLOWANCE AND FEE(S) DUE

44696

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04/01/2009

DR. MARK M. FRIEDMAN C/O BILL POLKINGHORN - DISCOVERY DISPATCH 9003 FLORIN WAY UPPER MARLBORO, MD 20772 EXAMINER

HELLING, KAITLYN ELIZABETH

PAPER NUMBER

ART UNIT

DATE MAILED: 04/01/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,135	12/23/2005	Ziv Karni	2922/14	5619

TITLE OF INVENTION: SYSTEM AND METHOD FOR HEATING BIOLOGICAL TISSUE VIA RF ENERGY

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	07/01/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

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If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450

Alexandria, Virginia 22313-1450 (571)-273-2885 or <u>Fax</u>

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for

maintenance fee notifications. Note: A certificate of mailing can only be used for domestic mailings of the CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. 44696 7590 04/01/2009 Certificate of Mailing or Transmission DR. MARK M. FRIEDMAN I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below. C/O BILL POLKINGHORN - DISCOVERY DISPATCH 9003 FLORIN WAY UPPER MARLBORO, MD 20772 (Depositor's name (Signature (Date APPLICATION NO. FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. FILING DATE 10/562,135 12/23/2005 Ziv Karni 2922/14 5619 TITLE OF INVENTION: SYSTEM AND METHOD FOR HEATING BIOLOGICAL TISSUE VIA RF ENERGY APPLN. TYPE SMALL ENTITY ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE DATE DUE nonprovisional YES \$755 \$300 \$0 \$1055 07/01/2009 **EXAMINER** ART UNIT CLASS-SUBCLASS HELLING, KAITLYN ELIZABETH 3739 607-100000 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). 2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. or agents OR, alternatively, (2) the name of a single firm (having as a member a ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment. (A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY) 4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) 4a. The following fee(s) are submitted: lssue Fee A check is enclosed. Publication Fee (No small entity discount permitted) Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number ______ (enclose an extra copy of this fo Advance Order - # of Copies _ (enclose an extra copy of this form). 5. Change in Entity Status (from status indicated above) a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ■ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2). NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office. Authorized Signature Date Typed or printed name Registration No. This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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10/562,135	12/23/2005	Ziv Karni	2922/14	5619
44696 7	590 04/01/2009		EXAM	INER
DR. MARK M. FRIEDMAN C/O BILL POLKINGHORN - DISCOVERY DISPATCH			HELLING, KAITLYN ELIZABETH	
			ART UNIT	PAPER NUMBER
9003 FLORIN WA UPPER MARLBO			3739 DATE MAILED: 04/01/200	9

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 768 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 768 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)
No.Co. of Allo object	10/562,135	KARNI ET AL.
Notice of Allowability	Examiner	Art Unit
	KAITLYN E. HELLING	3739
The MAILING DATE of this communication appeal all claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in this a or other appropriate communicati IGHTS. This application is subject	application. If not included on will be mailed in due course. THIS
1. X This communication is responsive to 12 March 2009.		
2. ☑ The allowed claim(s) is/are <u>1-40</u> .		
 Acknowledgment is made of a claim for foreign priority unanalysis. All b) ☐ Some* c) ☐ None of the: 1. ☐ Certified copies of the priority documents have 2. ☐ Certified copies of the priority documents have 3. ☒ Copies of the certified copies of the priority do International Bureau (PCT Rule 17.2(a)). * Certified copies not received: 	e been received. e been received in Application No.	
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.		ly complying with the requirements
 A SUBSTITUTE OATH OR DECLARATION must be subm INFORMAL PATENT APPLICATION (PTO-152) which give 		
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") mus (a) ☐ including changes required by the Notice of Draftspers 1) ☐ hereto or 2) ☐ to Paper No./Mail Date (b) ☐ including changes required by the attached Examiner' Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in the sheet. Grant of the position of the deposition of the de	son's Patent Drawing Review (PT s Amendment / Comment or in the84(c)) should be written on the dra the header according to 37 CFR 1.12 sit of BIOLOGICAL MATERIA	e Office action of wings in the front (not the back) of 21(d). L must be submitted. Note the
Attachment(s) 1. ☑ Notice of References Cited (PTO-892) 2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 3. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 01/24/2006, 03/29/2007, 12/31/2007, 01/25/2008, 03/11/2009, 03/12/2009 4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material	5. ☐ Notice of Informa 6. ☐ Interview Summa Paper No./Mail I 7. ☑ Examiner's Amer 8. ☑ Examiner's State 9. ☐ Other	iry (PTO-413), Date .
/KAITLYN E HELLING/ Examiner, Art Unit 3739		



Application No.

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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dr. Marc Van Dyke on March 12, 2009.

The application has been amended as follows:

1. The following is a replacement abstract:

A system 30 and method(s) 100 for thermal treatment of a selected target within a subject is disclosed. System 30 includes RF source 10, phase shifter 14, impedance matching network 11 and resonator 13. Applicator 3 conveys output signal 17 from energy source 10 through surface 6 of biological tissue 4 to predetermined energy dissipation zone 5 after output 17 has been processed by the phase shifter 14, IMN 11 and resonator 13. Stationary water molecules 1, such as those in fat cells, are heated. System 30 is operative to heat a volume of biological tissue beneath the biological tissue surface 6 such that surface 6 of biological tissue 4 is maintained at a lower temperature than predetermined energy dissipation zone 5 without a cooling device. The invention is useful in selective heating of cellulite bodies as a means of treating cellulite.

- 2. The following are amendments to the specification with respect to the originally filed Specification of December 23, 2005:
 - a. On Page 1, line 9: change "obviate the need for cooling of the skin surface while facilitating" to -- facilitate--.

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b. On Page 1, lines 22-24: change "These techniques have not demonstrated clinical efficacy" to -- These techniques have demonstrated various degrees of clinical efficacy--

Page 3

- c. On Page 1, lines 27-Page 2, line 2: change "However, previously available thermotherapy solutions share, as an inherent disadvantage, a tendency to heat the skin to the point of causing a burn when sufficient RF energy is applied to heat the fat cell target in the deepest skin layer." to --Non-invasive electromagnetic radiation, including radio-frequency waves, has been proposed in the prior art for treatment of fat and cellulite in addition to use for contraction of collagen, such as involved in the treatment of wrinkles.--
- d. On Page 2, line 3: change "currently accepted" to -- typical--
- e. On page 2, line 7: change "As a result, systems for implementation of this method share, as an inherent disadvantage, a strict requirement for a cooling mechanism to remove an excessive heat of the skin during treatment." To As a result, many of the conventional systems for implementation of this methods share, as an inherent disadvantage, a strict requirement for a cooling mechanism to remove an excessive heat of the skin during the treatment.--
- f. On Page 2, lines 10-11: delete "Previously available alternatives are characterized by disadvantages which are obviated by the present invention."
- g. On page 2, lines 18-19, change "Teachings of this patent have, as an inherent disadvantage, a strict requirement for cooling of the skin to prevent burning." to -- Teachings of this patent include a strict requirement for cooling of the skin to prevent burning.--
- h. On Page 2, lines 20-24: change "additional examples of prior art systems which require cooling of the skin to prevent burning include those disclosed in US Patent application No. 20040002705 assigned to Thermage, Inc. which teaches a method of creating a tissue effect by delivering electromagnetic energy through a skin surface from an electromagnetic energy device coupled to an electromagnetic energy source." to -- US Patent application No. 20040002705 assigned to Thermage, Inc. also discloses a system that required cooling of skin

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to prevent burning. In particular, this published patent application teaches a method of creating a tissue effect by delivering electromagnetic energy through a skin surface from an electromagnetic energy device coupled to an electromagnetic energy source.--

- i. On Page 2, lines 24 29: delete "At least one of the electromagnetic energy delivery device or electromagnetic energy source includes a memory. A reverse thermal gradient is created through the skin surface to sufficiently heat an underlying tissue site to provide that the temperature of the skin surface is lower than the temperature of the underlying tissue. The reverse thermal gradient is established by use of a cooling system, which is an inherent disadvantage."
- j. On Page 3, lines 5-6: change "as an inherent disadvantage" to --express--
- k. On Page 3, line 10: change "all previously available methods require the use of a cooling system" to -- the above described prior art methods require the use of a separate cooling system--
- I. On Page 3, lines 16-18: change "all previously available alternatives share, as an inherent disadvantage, a strict requirement for a return electrode" to -- the above described alternatives share, as strict requirement for a return electrode pad to be placed against the patient--
- m. On Page 3, line 24: change devoid of the limitation(s)" to -- that attempts to address one or more of the limitations of the above described systems--
- n. On Page 7, lines 11-13: change "Operation of the system produces a reverse thermal gradient so that the surface of the biological tissue is maintained at a lower temperature than the predetermined energy." To --Operation of the system heats a volume of biological tissue beneath the biological tissue surface so that the surface of the biological tissue is maintained at a lower temperature that the predetermined energy dissipation zone 5 without requiring a cooling device.--
- o. On Page 8, lines 5-7: change "Performance of (a)-(f) produces a reverse thermal gradient so that the surface of the biological tissue is maintained at a

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lower temperature than the predetermined energy dissipation zone, thereby obviating the need for a cooling device." to --Performance of (a)-(f) heats a volume of biological tissue beneath the biological tissue surface so that the surface of the biological tissue is maintained at a lower temperature than the predetermined energy dissipation zone 5 without requiring a cooling device.--

Page 5

- p. On Page 8, line 28-Page 9, line 3: change "Performance of (a)-(f) produces a reverse thermal gradient so that the surface of the biological tissue is maintained at a lower temperature than the predetermined energy dissipation zone, thereby obviating the need for a cooling device." to --Performance of (a)-(f) heats a volume of biological tissue beneath the biological tissue surface so that the surface of the biological tissue is maintained at a lower temperature than the predetermined energy dissipation zone 5 without requiring a cooling device.--
- q. On Page 14, lines 8-10: delete "Organization of energy dissipation inside of subcutaneous tissue insures maintenance of a relatively low temperature on the skin surface (epidermis). This provides a reverse thermal gradient without the use of an external cooling system."
- r. On Page 16, lines 10-13: delete "It is an inherent advantage of system **30** that its operation produces a reverse thermal gradient so that surface **6** of biological tissue **4** is maintained at a lower temperature than predetermined energy dissipation zone **5** without use of a cooling device."
- s. On Page 16, line 14: add --System **30** may be operated to heat a volume of biological tissue beneath the biological tissue surface **6** such that surface **6** of biological tissue **4** is maintained at a lower temperature than predetermined energy dissipation zone **5** without a cooling device. --
- t. On Page 16, line 25-Page 17, line 2: change "The temperature at surface 6 of tissue layer 4 is clearly lower than along line 26 in zone 5. In other words, operation of system 30 creates a reverse thermal gradient and obviates the need for a cooling system to prevent undesired overheating of surface 6." to -- In the example of Figure 4, the temperature at surface 6 of tissue 4 is clearly lower than along line 26 in zone 5.--

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u. On Page 17, line 10: delete "Despite the cooling system, no reverse thermal gradient is achieved."

- v. On Page 19, lines 18-20: change "Performance of 102, 104, 105, 108, 110 and 112 produce 114 a reverse thermal gradient so that surface 6 of biological tissue 4 is maintained at a lower temperature than predetermined energy dissipation zone 5, thereby obviating the need for a cooling device." to -- Performance of 102, 104, 105, 108, 110 and 112 heats biological tissue beneath the tissue surface 6 of biological tissue 4 so that the biological tissue surface 6 is maintained at a lower temperature than predetermined energy dissipation zone 5 without requiring a cooling device.--
- w. On Page 20, lines 19-20: delete "Applicator **3** serves also to cool tissue surface 6, thereby obviating the need for a separate cooling system."
- x. On page 21, lines 12-15: delete "It is an advantage of the present invention that epidermal layer **6** is heated mush less than subcutaneous tissue **4**. An inverse thermal gradient that is provided by intensive cooling of epidermis that described by Thermage patents is achieved automatically with deep heating of tissues."
- y. On Page 21, lines 7-8: delete "Thus, collagen capsules will be destroyed by heating because their high thermo isolation."
- z. On Page 21, lines 10-11: delete "will leads to the most efficient collagen capsule destruction"
- 3. The following are amendments to the claims with respect to the Preliminary Amendment filed April 30, 2007:
 - aa. Claim 1, lines 28-30: change "beneath said surface" to -- beneath said surface so that the surface of said biological tissue is maintained at a lower temperature than said predetermined energy dissipation zone without a cooling device--.
 - bb. Claim 20, lines 24-26: change" beneath said surface" to -- beneath said surface so that the surface of said biological tissue is maintained at a lower

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temperature than said predetermined energy dissipation zone without a cooling device--.

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cc. Claim 40, lines 26-28: change" beneath said surface" to -- beneath said surface so that the surface of said biological tissue is maintained at a lower temperature than said predetermined energy dissipation zone without a cooling device--.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: The closest prior art of record does not teach or fairly disclose a thermal treatment system that uses an RF energy source, a phase shifter, an impedance matching network, an RF resonator in which the system heats the biological tissue beneath the surface while the surface of the tissue is maintained at a lower temperature that the heated tissue beneath the surface *without* the benefit of a cooling device. All of the closest prior art utilizes an external cooling means such as a cooling fluid or thermoelectric cooling unites to reduce the temperature at the surface of the biological tissue being treated.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAITLYN E. HELLING whose telephone number is (571)270-5845. The examiner can normally be reached on Monday - Friday 7:30 a.m. to 5:00 p.m. EDT.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571)272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KAITLYN E HELLING/ Examiner, Art Unit 3739

/Roy D. Gibson/ Primary Examiner, Art Unit 3739